

## **THE PRODUCTION OF MEDICINES IN ROMANIA AFTER 1990. WHAT'S THE REASON FOR IMPORTS?**

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*Since 1990, Romania turned itself slowly but surely, from a large drugs producer, which has used to supply drugs to the whole former Council for Mutual Economic Assistance Member States, and with a net positive trade balance in medicine sector, into a large drugs importer, trying hardly to attract investors which could produce medicines not only for the Romanian domestic market, but also for all other Eastern European markets, Ukraine, Russia and Turkey.*

*This paper focuses on the empirical analysis of the medicines production sector in Romania after 1990, aiming to emphasise the factors which have mostly affected this industry, in correlation with different interests and reasons which determined the increasing imports of drugs during the last years, by underlying at the same time, the role of the new public authority in charge of supervising the distribution and import of medicines in Romania, The National Medicines Administration (NMA).*

*The paper relevance relies in the fact that Romania registered during the last years drug imports of an average of 1.7 billion euros, while the drug exports were only around 0,1 billions euros, according to the computations made on the data provided by the Romanian Institute of National Statistics (INS). The most imported products are patent drugs, which are more expensive than those produced by the domestic manufacturer. At the same time, Romania registered an increase of the pharmaceutical market of around 20% only since its EU integration, this market proven to be largely driven by expensive products.*

*Our research conducted to the conclusion that the Romanian resort authorities have to immediately adopt measures meant to limit consumption of expensive drugs, on the one side, and to reinforce the domestic manufacturers on the other side, even by attracting major investors in this sector. We have also identified that there is a large competitiveness for Romanian medicine products on the international market, due to its production costs (Romania still is a low cost economy in this sector), as well as due to its tradition.*

*Key words: drug manufacture, medicine production, Romanian economy, FDI, exports and imports*

*JEL Codes: F14, I12, L52, L65*

Pharmacies and pharmacists were among the first health care facilities and health professionals in Romania that were privatized or allowed to operate private businesses, respectively. Since 1998, the public authority in charge of supervising the distribution and import of drugs in Romania is The National Medicines Administration (NMA), which, according to its web site, authorizes both production and import of medicines in Romania, depending on their source: for import activities (i.e., import in Romania of medicines from extra-EEA countries), an import authorization is required; for distribution activities (i.e., distribution in Romania of drugs from EEA countries), a wholesale distribution authorization is issued. The orders issued by NMA in December 2008 regulate the procedure and conditions for the issuance of the import authorization or the wholesale authorization. The new regulatory framework establishes that a wholesale authorization is necessary even for merely invoicing the medicines.

Although Romanian drug production has drastically decreased after 1990, Romania has become during the last years of interest for the multinational companies producing drugs. For this reason, the Romanian drugs exports rose lately, but there still is a big gap between the imports and the exports of medicines: Romania registered during the last years drug imports of an average of 1.7 billion Euros, while the drug exports were only around 0.1 billion Euros, according to the computations made on the data provided by the Romanian Institute of National Statistics (INS) (see Table 1). As it concerns the imports, the main supplier is Hungary, followed very close by Germany and France.

**Table 1. Romanian imports and exports, 2006-2008**

<i>Code SITC REV.4</i>	<i>Year</i>	<b>Export FOB</b> <i>euro million</i>			<b>Import CIF</b> <i>euro million</i>		
		<b>2006</b>	<b>2007</b>	<b>2008</b>	<b>2006</b>	<b>2007</b>	<b>2008</b>
	<b>Total</b>	<b>25850</b>	<b>29549</b>	<b>33725</b>	<b>40746</b>	<b>51322</b>	<b>57240</b>
<b>5</b>	<b>Chemicals and related products, n.e.s.</b>	<b>1533</b>	<b>1693</b>	<b>2050</b>	<b>4581</b>	<b>5238</b>	<b>6185</b>
54	Medical and pharmaceutical products	108	87	163	1519	1495	1849

Data source: INS

Note: SITC, REV. 4 - Standard International Trade Classification.

If before 1990, there were only 4 big national drugs producers in Romania – Sicomed, Antibiotice, Terapia and Biofarm -, after 1990 those producers have been bought and modernised by foreign investors, which have also diversified their products' portofolio. As a result, some former national brands like Rinofug, Boicil or Ciocolax disappeared, while some others, like Faringosept, still have success, being exported to the old traditional markets, like Russia and Ukraine. For example, only in 2010, the exports of Faringosept produced by Terapia-Ranbaxy, part of the Daiichi-Sankyo group, to these markets, valued 13 mil. Euros out of the total of 15 mill. Euros exported.

The foreign investors own these days the biggest share of the Romanian generic drugs production, being strategic partners of the Romanian public health system, confronted with big financial issues, which lead in 2010, to a change in the national legislation

permitting the creation of a partnership between the public authorities and the business environment. This partnership is based on the compensation mechanism which is in favour of the generic drugs, meant to save the incomes to the public budget. From this perspective, by the end of 2011, the investments of the generic drugs producers in Romania are expected to grow more over 2 bn. Euros as it was registered at the end of 2010, but these investments must be oriented to human resources, licences, and the development of the home production facilities, in order to produce the expected positive results.

Pharmaceutical manufacturing, distribution systems and quality are controlled by legislation, there being no formal pharmaceutical policy in Romania, but only tools for regulating the pharmaceutical market and its links with the health care system (NMA web site).

Production is inspected by the NMA, while distribution warehouses and pharmacies are inspected by the Ministry of Health and the counties' public health authorities (CPHAs). Producers cannot have their own wholesale distribution or pharmacies. The government has only two facilities where the state (Ministry of Health) still holds a share: Antibiotice Iasi (producer of generic drugs, mainly antibiotics) and Unifarm (distributor). These facilities do not benefit from any protectionist measures and compete with all other existing private companies in Romania. The latest ones have registered good results so far in Romania: 8 companies - Terapia-Ranbaxy, Antibiotice, Biofarm, Gedeon-Richter, Labormed, Actavis, Sandoz and Zentiva – had 0.4 bn. Euros turnover only in 2009, while having a total of over 7.500 employees.

Hospitals are supplied with drugs by wholesalers, and purchasing is regulated by the public acquisition law. According to the NMA, commercial relations between wholesalers and retailers (pharmacies) are not regulated except for ensuring that the wholesaler mark-up does not exceed 9%.

The Romanian Ministry of Health is responsible for the registration and licensing of pharmacies. The total number of pharmacies in 2010 licensed and registered was more than 6000. Out of these, approximately 75% had contractual relations with a health insurance fund, but only contracted pharmacies are permitted to sell drugs that are included in the public compensation scheme. The criteria used to select these pharmacies are as follows: professional qualifications of the employees and the accessibility to potential beneficiaries (patients). In urban areas, there were more than 75% out of total pharmacies registered while in rural areas are the rest.

Drug registration is the responsibility of the NMA, where data exclusivity operates according to the European Union requirements. Bolar provision operates too, but compulsory licensing was never used. The regulations are compliant with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In present, approximately 7000 drugs are registered in Romania, and there are some 100 new applications for registration every month.

The continuing rise in cost of medicines during the transition period has caused increased concern to the Ministry of Health and the Government in general, but however, measures for cost-containment and drug regulation have been introduced on an ad hoc basis. According to the drug law, the Ministry of Health establishes the maximum retail prices of both locally produced or imported pharmaceutical products, with the exception of over-the-counter (OTC) drugs. Prices for these drugs are not regulated by Ministry of

Health, these being freely sold on the market. However producers or importers of OTC drugs need to notify the Ministry of Health about prices of their products on a quarterly basis.

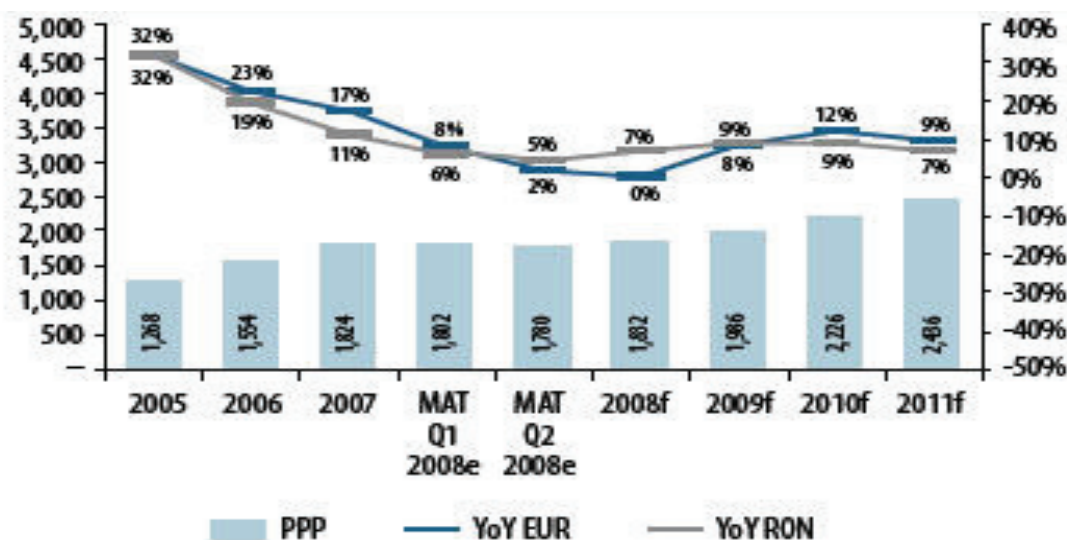
The NMA gives approval for alternative/complementary medicines to be marketed but the Ministry of Health does not regulate their prices. After a new drug is registered at the NMA, the Ministry of Health gives it a price before the product is allowed to be marketed in Romania. For drugs that are already registered, producers also need to apply to Ministry of Health for a price if a price increase is requested. When requesting a price increase, producers are usually simply changing the packaging size or size of tablets. Permission for price increase is seldom granted.

Producers and importers have to present their manufacturer price to the Ministry of Health. Importers are asked for the price from country of origin and the price for which they have bought the product (cost, insurance and freight price), while local producers are asked for the level of production costs, profit and wholesaler price. Based on information provided by the importer or producer, prices are usually compared with prices of the same product already on the market in the following countries: the Czech Republic, Bulgaria, Hungary and, if necessary, Austria, Belgium, Italy, Poland and Slovakia. The lowest price is considered. No other comparison tools are used. Both importer and local producers are allowed to take a gross profit margin of 7.5%. Only the importer can add a further mark-up of 8.5% for services connected to the import. The total mark-up for imported drugs was 30% until 2003; since then it has gradually decreased.

Price adjustments can take place on a yearly basis by applying a formula that takes into account the currency exchange rates between the adjustment dates. Prices are published in a drug catalogue that is updated quarterly and it is available on Internet, at the web address [www.msf-dgf.ro](http://www.msf-dgf.ro).

The mark-up of the wholesaler and the pharmacist is dependent on the price of the package (usually one-month's supply of medication). Some importers give discounts to wholesalers; wholesalers give discounts to pharmacists, and the total mark-up of the wholesaler and pharmacist varies from 12% for prices over €2.14 and 24% for prices below €0.5.

In Romanian, there is an increasing domestic demand of drugs, which will keep the foreign investors in the country. According to the Romania Pharmaceuticals and Healthcare Report, which provides data and forecasts about the Romanian market, the total pharmaceutical sales in Romania, in 2010, were around RON10.78bn (2.5 bn Euros), making Romania the seventh-largest market in Emerging Europe (see Figure 1).



**Figure 1. The Evolution of the Romanian Pharmaceutical Market**

Source: <http://rbd.doingbusiness.ro/ro/1/articole-recente/1/94/romanian-pharmaceutical-market>, accessed in January 2011

Labormed was the first greenfield investor in the Romanian drugs industry, and initially invested 19 mill. Euros in 2007. Thereafter, Labormed was bought by the Advent International Investment Fund. At that time, the surface of the factory was of about 10.000 qm., had 230 employees, a production capacity of 60000 commercial units per year, and a portfolio of 216 products, out of which 162 for the internal market. Its most successful export product is Prostacare plus, mainly sold on the Polish market.

A big domestic producer is Sanofi-Aventis / Zentiva, which has a production capacity of over 100 mill. Commercial units per year, and annual investments of 10 mill. Euros, which will continue in the next years.

Actavis is another producer of drugs in Romania, which employed over 150 specialists and produce over 2 mill. commercial units of oncological drugs per year, out of which 40% are for domestic market. The top exported Actavis products are Gemcitabina, Irinotecan and Fludarabina, produced mainly by the Sindan Pharma factory of the Actavis. This top international producer and dealer of generic drugs have also acquired other former Romanian drugs factories, such as Antibiotice Iasi and Terapia Cluj-Napoca, as well as new factories developed after 1990, like Sandoz and Gedeon-Richter in Targu-Mures, and Europharm-GSK in Brasov.

GSK produces medicaments both for internal and external markets, currently exporting in more than 50 countries across the globe. In 2010, its exports represented 43% of the total production, equivalent of 18.5 mill. commercial units. Since 2008, its exports rose with 186% in 2009 compared to 2008, and in 2010, with 330% compared to 2009. These results are due to those over 100 mill. Euros invested by the company in Romania during the last 12 years.

Other drugs producers are located in Targu-Mures, where Sandoz and Gedeon Richter have established their production units. In 1998, Gedeon Richter acquired Armedica S.A., which was renamed Gedeon Richter Romania S.A. in 2003, and has in present over 550

employees, out of which more than a half have University degrees. Its top exported products are tamsulosina, simvastatina and haloperidolul. Sandoz also exports a big share of its production in Romania.

With all lately foreign investments in Romania, the country is at the bottom of the top of the country with biggest research investments in drugs production and development, with only 5 Euros per capita in average, during the last 5 years, similar to Portugal and Greece, and opposite to Denmark (190 Euros per capita), Belgium (170 Euros per capita), and Sweden (80 Euros per capita). From this point of view, Romania certainly does not have the dilemma of the most developed countries, which have to deal with issues like opting for encouraging the innovation or limiting the increase of the health expenditure (Giurgiu, 2008).

### **Conclusion**

Because of the fact that Romania has a European minimum price for the drugs to sell, there is an even bigger market for the re-exports and parallel exports, which means that the drug is imported in Romania to the minimum price in the EU, and then is re-exported to other markets, to be sold at a higher price. Unfortunately, also the generic drugs are exported to foreign markets, only because the Romanian government insisted that these drugs to be sold at the lowest European price, even for the innovator drugs. The situation resulted in a paradox of the Romanian drugs market: the domestic producers prefer to export, due to the export prices and to the fact that the government reimburse the domestic producers with a nine months delay, while the domestic population, due to the lack of domestic drugs, buy imports drugs, which are very expensive. By consequence, as long as the domestic producers receive the money from the Romanian budget with a 9 months delay, the export will represent their only way to enhance the cash-flow.

Romania has some strength which could encourage the foreign investors to further produce drugs in the country, such as: tradition in producing drugs, specialised labour force, and good potential to raise the internal consumption. It must consider also the average domestic consumption which is about 100 Euros per year, while the region average is around 250 Euros per year, suggesting that in Romania there still is much potential for this market, both in volume and value. Furthermore, Romania is between those 17 emerging markets which, according to the IMS Health forecasts, will raise their turnover with more than 90 bn. Euros till 2013, contributing this way to an increase of the global pharmaceutical market of around 48% in 2013.

Besides, it has to be further considered the fact that in order to attract foreign investments, the law and the economic system are very important, both representing the weakness of Romania, because of their instability.

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